REMARKS/ARGUMENTS

Applicants herein traverse and respectfully request reconsideration of the rejection of the claims in view of the following remarks.

Claims 34-42 are pending in the application. Claims 34-42 have been rejected. Claim 34 has been amended. Support for the amendment to Claim 34 is found in the specification on Page 2, the second full paragraph from the bottom of the page. No new matter has been added. Entry of the foregoing amendment is respectfully requested.

Claims 34-42 have been rejected under 35 U.S.C. §103(a) as being unpatentable over U.S. Patent 5,048,727 (Vlasich) in view of U.S. Patent 3,709,365 (Czaplinski et al.) In particular, the Examiner states on pages 2-3:

> "Vlasich discloses a pharmaceutical package as seen in figure 1, which comprises a closed polypropylene bottle/barrel (12) in which is disposed a solution (15), the solution comprises a pharmaceutical product (col. 2, ll. 57-64), wherein the solution does not fill the bottle completely and some air is disposed in the bottle (col. 3, ll. 34-39). Vlasich lacks after autoclaving the package at at least 121°C and for at least 20 minutes, suffers no deformation, does not shrink, and does not explode and where the package retains a sufficiently high squeezability to dispense the solution. Czaplinski et al. teach the use of autoclaving a polypropylene material at about 115 -125°C. from 20-30 minutes (col. 2, ll. 49-58).
>
> It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify Vlasich's package by autoclaving the package, as taught by Czaplinski et al. in (col. 2, ll. 49-58) in order to treat a material that can withstand autoclaving at a temperature 121°C for at least 20 minutes."

Applicants respectfully disagree with the Examiner's conclusion and assert that the combined cited references do not make obvious the claimed subject matter as defined in amended independent Claim 34.

At the outset, it is noted that the Examiner bears the initial burden of proving a *prima facie* case of obviousness. This burden can be met by showing some objective teaching in the prior art or that knowledge that is available to one of ordinary skill in the art would motivate that individual to combine the relevant teachings of the references. In re Fritch, 972 F.2d 1260, 1265, 23 U.S.P.Q. 2d 1780, 1783 (Fed. Cir. 1992) [citing In re Piasecki, 745 F.2d 1468, 1471-72, 223 U.S.P.Q. 785, 787-88 (Fed. Cir. 1984)]. The Applicant can rebut the Examiner's *prima facie* case of obviousness by showing it was improperly made out, or by providing objective evidence which supports a conclusion of nonobviousness. *Id.* at 1265 citing In re Heldt, 433 F.2d 808, 811, 167 U.S.P.Q. 676, 678 (CCPA 1970).

With particular relevance to the present application, MPEP §2141 (Basic Considerations Which Apply to Obviousness Rejections, a copy of which is attached hereto) states:

> "When applying 35 U.S.C. §103, the following tenets of patent law must be adhered to:
>
> (A) The claimed invention must be considered as a whole;
>
> (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;
>
> (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention...."

As demonstrated below, a *prima facie* case of obviousness has not been established. Before discussing the reasons for Applicants' conclusion, a brief summary of the presently claimed pharmaceutical package is set forth below.

The presently claimed pharmaceutical package as defined in amended independent Claim 34 comprises a closed polypropylene bottle in which is disposed a solution or gel comprising a pharmaceutical product. The solution or gel does not fill the bottle completely and some air is disposed in the bottle. The package upon autoclaving at at least 121°C for at least 20 minutes suffers no deformation, does not shrink or explode and retains a sufficiently high squeezability to dispense one drop at a time the solution or gel.

Reasons That a *Prima Facie* Case of Obviousness Has Not Been Established

1. Vlasich, when considered as a whole, fails to teach or suggest the presently claimed pharmaceutical package.

   In considering the presently claimed pharmaceutical package and the teachings of Vlasich, the Examiner's attention is directed to MPEP §2141.02 (a copy of which is attached hereto) which indicates that when ascertaining the differences between the prior art and the claims at issue, not only must the claimed invention be considered as a whole, but also the prior art reference must be considered in its entirety, i.e., as a whole,...

   In the present case, the Examiner has not considered the teachings pertaining to Vlasich dispenser in its entirety as is evidenced first by the Examiner's characterization of the Vlasich dispenser as being:

   > "a closed polypropylene bottle/barrel (12) in which is disposed a solution (15), the solution comprises a pharmaceutical product (col. 2, ll. 57-64), wherein the solution does not fill the bottle completely and some air is disposed in the bottle (col. 3, ll. 34-39)."

When considering the teachings of Vlasich in its entirety, the dispenser described in Vlasich is not a closed polypropylene bottle which contains both a pharmaceutical solution and some air as is asserted by the Examiner. Instead, the single dose dispenser of Vlasich (see column 2, lines 16-32 and column 3, lines 34-67) is made up of two different chambers:

- a flexible chamber containing a gas propellant such as air; and
- a rigid chamber containing a product.

The complete structure of the dispenser and its operation are shown in Figure 1 and described in column 2, lines 16-56 and column 3, lines 34-68 to column 4, lines 1-45. As set forth in Vlasich, a compressible container (12) (the flexible chamber) is filled with a gas propellant (13) such as air, and a product dispensing storage tube (14) (the rigid chamber) is filled with a predetermined dose of a composition (15) to be dispensed. The tube (14) includes a discharge opening (19) and is connected to the compressible container (12). By compressing the container (12) the air contained therein is forced to flow into the tube (14) to displace the composition (15) from the tube through the discharge opening (19). The wall (20) of the container (12) is made of a material having sufficient flexibility such as polyethylene, polypropylene, polyvinyl chloride, copolymers and the like, to permit it to bow inwardly upon application of finger pressure. The tube side wall (24) is of sufficient rigidity to resist the tendency to blow upon application of finger pressure. The composition (15) is thus prevented from being inadvertently squeezed into the container (12) filled with air.

In contrast to the two-chamber dispenser of Vlasich wherein the air and composition are in two different chambers and the two different chambers are made of different materials, the presently claimed pharmaceutical package comprises a closed bottle, i.e., one chamber, made of polypropylene, wherein the one chamber, the bottle, has disposed therein both a solution or gel comprising a pharmaceutical product and air.

Other statements made by the Examiner with respect to the Vlasich dispenser also demonstrate that the Examiner has not considered the entire teachings of Vlasich. Specifically, the Examiner at Page 2 of the final action states:

> "Vlasich lacks after autoclaving the package at at least 121°C and for at least 20 minutes, suffers no deformation, does not shrink, and does not explode and where the package retains a sufficiently high squeezability to dispense the solution."

Vlasich, however, makes clear in Figure 2, the Brief Description of the Drawings for Figure 2, and column 3, lines 5-11, that once the wall (20) of the container (12) is compressed all the air in the container is displaced and the container is in a collapsed state to dispense the entire unit dose of the product contained in the tube (14).

Indeed, the teachings of Vlasich point toward the fact that once the container (12) of the dispenser is compressed and the air flows out, the container and tube components of the dispenser remain in a collapsed state since all the air is pushed out into the tube (14) component of the dispenser. Accordingly, in contrast to the Examiner's assertion that the Vlasich dispenser suffers no deformation and retains sufficient squeezability, the two-chamber Vlasich dispenser upon discharging an entire dose of product is in a collapsed state and thus is deformed and does not retain sufficient squeezability.

As acknowledged by the Examiner there is no teaching or specific suggestion in Vlasich of autoclaving the dispenser containing the composition at at least 121°C. Indeed, Vlasich is merely concerned about the problem of dispensing an entire predetermined dosage in one discharge. Vlasich has no concern whatsoever and is completely silent regarding the problem of retaining sufficient squeezability of a pharmaceutical package upon autoclaving so that the solution or gel in the bottle can be dispensed repeatedly one drop at a time. Indeed, there is no need for the single unit dosage dispenser of Vlasich to retain sufficient squeezability as is evidenced by the purpose of such a dispenser, to discharge an entire unit dosage at one time, and the collapsed state of the dispenser upon discharging an entire dosage.

Moreover, the Vlasich dispenser is utilized one time to dispense an entire unit dosage. In contrast, the presently claimed pharmaceutical package is utilized repeatedly to dispense one drop at a time the solution or gel comprising the pharmaceutical product.

Since Vlasich when considered in its entirety, describes a dispenser possessing a completely different structure, operation and purpose from the presently claimed pharmaceutical package, it can be fairly stated that Vlasich fails to teach or specifically suggest the presently claimed pharmaceutical package as set forth in amended Claim 34.

Further, even assuming arguendo the Examiner were to assert that it would be obvious to modify the Vlasich dispenser to arrive at the presently claimed pharmaceutical package, it is asserted that such modifications would not be obvious. The Federal Court on the issue of obvious 'modifications' has instructed that:

> "The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification."
> *Id.* at Page 1226 [citing In re Gordon, 733 F.2d at 902, 221 U.S.P.Q. at 1127]

In the present case as stated above, there is no teaching or specific suggestion to modify the structure of the single dose, two-chamber dispenser described in Vlasich to a multi-dose pharmaceutical package comprising a one-chamber polypropylene bottle which has

retained a sufficiently high squeezability upon autoclavation to dispense one drop at a time the solution or gel comprising the pharmaceutical product as set forth in amended Claim 34. Further, as stated above, there is no teaching or suggestion in Vlasich to autoclave the dispenser nor is there a concern to solve the problem of autoclaving a pharmaceutical package so that it still retains a sufficient squeezability to dispense one drop at a time a solution or gel containing the product. Accordingly, Vlasich fails to suggest the desirability of such a modification.

Indeed, if the Vlasich dispenser were modified to the presently claimed pharmaceutical package comprising a polypropylene bottle suffering no deformation and retaining a sufficiently high squeezability, the modified dispenser would arguably be rendered unsatisfactory for its intended purpose, i.e., to dispense an entire dosage in a single discharge. With regard to modifying the prior art invention to arrive at the claimed invention, the Federal Court has held that if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. In re Gordon, 733 F.2d 900, 221 U.S.P.Q. 1125 (Fed. Cir. 1984).

2) Vlasich teaches away from the presently claimed pharmaceutical package by teaching a two-chamber dispenser for dispensing at one time a single dose of a pharmaceutical preparation.

It is well settled that a determination of obviousness not only requires that the claimed invention be read as a whole, but also that the prior art reference be read as a whole and that:

> "consideration must be given where the references diverge and teach away from the claimed invention."
>
> Akzo N.V. v. United States Intl Trade Commission, 808 F.2d 1471, 1481, 1 U.S.P.Q. 2d, 1241, 1246 (Fed. Cir. 1986), *cert. denied*, 482 U.S. 909 (1987).

The Federal Court has instructed that a prior art reference "teaches away" when one of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the prior art reference, or alternatively, would be led in a direction divergent from the path that was taken by the applicant. In re Gurley, 31 U.S.P.Q. 2d 1131 (Fed. Cir. 1994).

In view of the above instruction, it can fairly be said that Vlasich, in teaching a two-chamber dispenser that collapses upon discharge of an entire dosage at one time, i.e., a dispenser that suffers deformation and loss of sufficient squeezability, specifically teaches away from the presently claimed pharmaceutical package comprised of a closed polypropylene bottle which suffers no deformation and which retains sufficiently high

squeezability for repeated use so that it can easily dispense one drop at a time the solution or gel comprising the pharmaceutical product. Accordingly, one skilled in the art armed with the teaching of Vlasich would be led in a direction divergent from the path that was taken by the Applicants, that is, one skilled in the art would not have chosen to construct a pharmaceutical package that retains sufficient squeezability to repeatedly dispense one drop at a time a solution or gel containing a pharmaceutical product.

3) The teachings of Czaplinski et al. when considered as a whole and combined with Vlasich fail to teach or specifically suggest the presently claimed pharmaceutical package, and thus fail to suggest the desirability of and thus the obviousness of combining Vlasich with Czaplinski et al.

Czaplinski et al. describe a radioactive generator system having a sterile, sealed disposable closure therein. As shown and described in Figure 1 and column 2, lines 3-62 of Czaplinski et al., the generator system (4) is connected to an elution bottle (12) containing an elution solution (10) via a hypodermic needle. The details of the generator system (4) are more fully set out in U.S. Patent 3,369,121 (Bruno et al., a copy of which is attached) which is referenced in Czaplinski et al. (see column 2, lines 9-11). As described in Bruno et al., the generator system houses a column which has bound to it radioactive material (see columns 2 and 3). As further described in Bruno et al. (see column 3, lines 62-75), the column, prior to its insertion in the generator system, is filled with a radioactive solution. Most of the radioactive material is absorbed onto the column and the excess radioactive material and water pass through the column and are removed. The column is then washed with acid and saline to remove any non-absorbed radioactivity and the column is sterilized, as by autoclaving. Following autoclaving, the sterilized column containing the bound radioactive material is inserted into the body of the generator.

As further described in Czaplinski et al. (see column 2, lines 3-62), the eluting solution contained in the elution bottle which is hooked up to the generator system flows through the sterilized column of the generator system and the eluate containing the radioactive material is removed via a hypodermic needle from the bottom of the generator system and allowed to pass through conduit (22) into sterile closure (30) and then through conduit (24) into vial (20).

The sterile closure (30) comprises *inter alia*, a housing (42) wherein one end is closed by a pierceable membrane and the opposite end remains open, a membrane filter placed between the membrane and the open end, and a seal around the closed end of the housing (42) to retain the membrane in position. The purpose of the sterile closure (30)

is to ensure sterility at the site of delivery of the radioactive material and reduce contamination of the generator system (see Czaplinski et al., column 1, lines 41-50).

While Czaplinski et al. (see column 2, lines 49-55) indicate that the housing material (42) can be made of a plastic, e.g., polypropylene or metal material which withstands autoclaving, e.g., about 115-125°C, it is apparent from reading Czaplinski et al., that the sterile closure (30) comprising *inter alia* the housing material (42) made of plastic or metal is sterilized prior to being connected to conduits (22) and (24) to ensure sterility at the site of delivery of the radioactive material. Importantly, Czaplinski makes clear that the radioactive material eluting from the column has already been sterilized prior to its elution from the column and is not sterilized at 115-125°C when it passes through the housing material (42) of the sterile closure (30). Thus, the radioactive material eluted from the column is not contained in the closure (30) when the closure (30) was previously sterilized. Accordingly, Czaplinski et al. fails to teach or specifically suggest autoclaving a pharmaceutical package comprising a closed polypropylene bottle which had disposed a solution or gel comprising a pharmaceutical product and air. Czaplinski et al., also fails to teach or specifically suggest that such a pharmaceutical package suffers no deformation and retains a sufficiently high squeezability to dispense one drop at a time the solution or gel. As stated above, Czaplinski et al. is merely concerned with the problem of ensuring sterility at the site of delivery of the radioactive material and to reduce contamination of the generator system. Accordingly, Czaplinski et al., as a whole, does not teach or suggest the presently claimed pharmaceutical package.

In sum, Vlasich, as a whole, teaches a two-chamber dispenser made of a flexible container containing only air and a rigid tube containing the pharmaceutical composition, which dispenser upon discharging the entire dosage at one time collapses. Vlasich is deficient *inter alia* in teaching or suggesting autoclavation of such a dispenser, and that the dispenser when autoclaved suffers no deformation and retains a sufficiently high squeezability to dispense one drop at a time the pharmaceutical composition. In addition, Vlasich, teaches away from the presently claimed pharmaceutical package, by teaching a two-chamber dispenser that discharges at one time an entire dosage, and that following discharge of the dosage from the dispenser, the dispenser is in a collapsed state and thus suffers deformation and loses a sufficiently high squeezability. Further, if the Vlasich dispenser was modified to the presently claimed pharmaceutical package, the modification would arguably render the dispenser inoperable for its intended purpose, i.e., to discharge an entire unit dosage at one time.

Czaplinski et al., as a whole, while describing a radioactive generator system, which system *inter alia* includes a housing material made of plastic, the housing material is actually autoclaved prior to placement between conduits (22) and (24) of the generator

system, and thus the radioactive solution is not contained in the housing material upon autoclavation. Accordingly, Czaplinski et al. is deficient in teaching or suggesting the elements missing from Vlasich, i.e., a closed polypropylene bottle which is disposed a solution or gel and some air, which upon autoclaving suffers no deformation and retains a sufficiently high squeezability to dispense one drop at a time the solution or gel.

Accordingly, it is difficult to see how Vlasich and Czaplinski et al. when viewed as a whole suggest the desirability of and thus the obviousness of combining Vlasich and Czaplinski et al. to arrive at the presently claimed invention as defined in amended Claim 34.

4) The §103 rejection is based on hindsight reconstruction.

It is respectfully submitted that the Examiner is relying upon hindsight to arrive at the determination of obviousness by picking and choosing separate components of the prior art references and using them to piece together the claimed subject matter without evaluating the references as a whole. The Federal Circuit has held that:

> "Obviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination....The mere fact that the prior art may be modified in the manner suggested by the Examiner does not make the modification obvious unless the prior art suggested the desirability of the modification.
>
> It is impermissible to use the claimed invention as an instruction manual or template to piece together the teachings of the prior art so that the claimed invention is rendered obvious. One cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention.
>
> In re Fritch, 23 U.S.P.Q. 1781, 1783, 1784 (Fed. Cir. 1992).

Indeed, the Federal Circuit has repeatedly cautioned against using hindsight by using the Applicants' disclosure as a blueprint to reconstruct the claimed subject matter out of isolated teachings from the prior art. See also Grain Processing Corp. V. American Maize-Products Co., 840 F.2d 902, 5 U.S.P.Q. 2d 1788 (Fed. Cir. 1988).

Since as discussed above, 1) Vlasich fails to teach or suggest a pharmaceutical package comprising a closed polypropylene bottle which is disposed both a solution or gel and air, wherein the bottle upon autoclavation suffers no deformation and retains a sufficiently high squeezability to dispense one drop at a time a solution or gel; 2) Vlasich teaches away from a pharmaceutical package dispensing one drop at a time a solution or gel and wherein such package suffers no deformation and retains sufficient squeezability; and 3) Czaplinski et al. fails to teach the elements that are deficient in Vlasich, it is clear that the Examiner has used

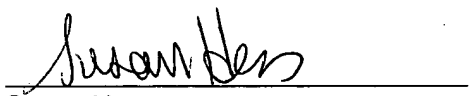
hindsight to pick and choose among the isolated disclosures of the prior art to deprecate the present claims.

Accordingly, Vlasich and Czaplinski et al., each taken alone or combined, do not make obvious the pharmaceutical package defined in amended independent Claim 34.

In view of the above, withdrawal of the rejection of Claims 34-42 under 35 U.S.C. §103(a) is respectfully requested.

A good faith effort has been made to place the present application in condition for allowance. If the Examiner believes a telephone conference would be of value, he is requested to call the undersigned at the number listed below.

Respectfully submitted,



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STANDARD OF PATENTABILITY TO BE APPLIED IN OBVIOUSNESS REJECTIONS

Patent examiners carry the responsibility of making sure that the standard of patentability enunciated by the Supreme Court and by the Congress is applied in each and every case. The Supreme Court in *Graham v. John Deere*, 383 U.S. 1, 148 USPQ 459 (1966), stated:

> Under § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented. As indicia of obviousness or nonobviousness, these inquires may have relevancy. . .
>
> This in not to say, however, that there will not be difficulties in applying the nonobviousness test. What is obvious is not a question upon which there is likely to be uniformity of thought in every given factual context. The difficulties, however, are comparable to those encountered daily by the courts in such frames of reference as negligence and scienter, and should be amenable to a case-by-case development. We believe that strict observance of the requirements laid down here will result in that uniformity and definitiveness which Congress called for in the 1952 Act.

Office policy is to follow *Graham v. John Deere Co.* in the consideration and determination of obviousness under 35 U.S.C. 103. As quoted above, the four factual inquires enunciated therein as a background for determining obviousness are as follows:

(A) Determining the scope and contents of the prior art;

(B) Ascertaining the differences between the prior art and the claims in issue;

(C) Resolving the level of ordinary skill in the pertinent art; and

(D) Evaluating evidence of secondary considerations.

The Supreme Court reaffirmed and relied upon the *Graham* three pronged test in its consideration and determination of obviousness in the fact situations presented in *Sakraida v. Ag Pro, Inc.*, 425 U.S. 273, 189 USPQ 449, *reh'g denied*, 426 U.S. 955 (1976) and *Anderson's-Black Rock, Inc. v. Pavement Salvage Co.*, 396 U.S. 57, 163 USPQ 673 (1969). In each case, the Court discussed whether the claimed combinations produced a "new or different function" and a "synergistic result," but it clearly decided whether the claimed inventions were nonobviousness on the basis of the three-way test in *Graham*. Nowhere in its decisions in these cases does the Court state that the "new or different function" and "synergistic result" tests supersede a finding of nonobvious or obviousness under the *Graham* test.

Accordingly, examiners should apply the test for patentability under 35 U.S.C. 103 set forth in *Graham*. See below for a detailed discussion of each of the *Graham* factual inquiries. It should be noted that the Supreme Court's application of the *Graham* test to the fact circumstances in *Ag Pro* was somewhat stringent, as it was in *Black Rock*. Note *Republic Industries, Inc. v. Schlage Lock Co.*, 592 F.2d 963, 200 USPQ 769 (7th Cir. 1979). The Court of Appeals for the Federal Circuit stated in *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 1540, 218 USPQ 871, 880 (Fed. Cir. 1983) that

> A requirement for "synergism" or a "synergistic effect" is nowhere found in the statute, 35 U.S.C. When present, for example in a chemical case, synergism may point toward nonobviousness, but its absence has no place in evaluating the evidence on obviousness. The more objective findings suggested in *Graham*, supra, are drawn from the language of the statute and are fully adequate guides for evaluating the evidence relating to compliance with 35 U.S.C. § 103. *Bowser Inc. v. United States*, 388 F. 2d 346, 156 USPQ 406 (Ct. Cl. 1967).

BASIC CONSIDERATIONS WHICH APPLY TO OBVIOUSNESS REJECTIONS

When applying 35 U.S.C. 103, the following tenets of patent law must be adhered to:

(A) The claimed invention must be considered as a whole;

(B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination;

(C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and

(D) Reasonable expectation of success is the standard with which obviousness is determined.

Hodosh v. Block Drug Co., Inc., 786 F.2d 1136, 1143 n.5, 229 USPQ 182, 187 n.5 (Fed. Cir. 1986).

OBJECTIVE EVIDENCE MUST BE CONSIDERED

Objective evidence or secondary considerations such as unexpected results, commercial success, long-felt need, failure of others, copying by others, licensing, and skepticism of experts are relevant to the issue of obviousness and must be considered in every case in which they are present. When evidence of any of these secondary considerations is submitted, the examiner must evaluate the evidence. The weight to be accorded to the evidence depends on the individual factual circumstances of each case. *Stratoflex, Inc. v. Aeroquip Corp.*, 713 F.2d 1530, 218 USPQ 871 (Fed. Cir. 1983); *Hybritech, Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (Fed. Cir. 1986), *cert. denied*, 480 U.S. 947 (1987). The ultimate determination on patentability is made on the entire record. *In re Oetiker*, 977 F.2d 1443, 1446, 24 USPQ2d 1443, 1445 (Fed. Cir. 1992).

See MPEP § 716- § 716.06 for a discussion of objective evidence and its role in the final legal determination of whether a claimed invention would have been obvious under 35 U.S.C. 103.

2141.01 Scope and Content of the Prior Art

I. PRIOR ART AVAILABLE UNDER 35 U.S.C. 102 IS AVAILABLE UNDER 35 U.S.C. 103

"Before answering *Graham's* 'content' inquiry, it must be known whether a patent or publication is in the prior art under 35 U.S.C. § 102." *Panduit Corp. v. Dennison Mfg. Co.*, 810 F.2d 1561, 1568, 1 USPQ2d 1593, 1597 (Fed. Cir.), *cert. denied*, 481 U.S. 1052 (1987). Subject matter that is prior art under 35 U.S.C. 102 can be used to support a rejection under section 103. *Ex parte Andresen*, 212 USPQ 100, 102 (Bd. Pat. App. & Inter. 1981) ("it appears to us that the commentator [of 35 U.S.C.A.] and the [congressional] committee viewed section 103 as including all of the various bars to a patent as set forth in section 102.").

A 35 U.S.C. 103 rejection is based on 35 U.S.C. 102(a), 102(b), 102(e), etc. depending on the type of prior art reference used and its publication or issue date. For instance, an obviousness rejection over a U.S. patent which was issued more than 1 year before the filing date of the application is said to be a statutory bar just as if it anticipated the claims under 35 U.S.C. 102(b). Analogously, an obviousness rejection based on a publication which would be applied under 102(a) if it anticipated the claims can be overcome by swearing behind the publication date of the reference by filing an affidavit or declaration under 37 CFR 1.131.

For an overview of what constitutes prior art under 35 U.S.C. 102, see MPEP § 901 - § 901.06(d) and § 2121 - § 2129.

II. SUBSTANTIVE CONTENT OF THE PRIOR ART

See MPEP § 2121 - § 2129 for case law relating to the substantive content of the prior art (e.g., availability of inoperative devices, extent to which prior art must be enabling, broad disclosure rather than preferred embodiments, admissions, etc.).

III. CONTENT OF THE PRIOR ART IS DETERMINED AT THE TIME THE INVENTION WAS MADE TO AVOID HINDSIGHT

The requirement "at the time the invention was made" is to avoid impermissible hindsight. See MPEP § 2145, paragraph X.A. for a discussion of rebutting applicants' arguments that a rejection is based on hindsight.

"It is difficult but necessary that the decisionmaker forget what he or she has been taught . . . about the claimed invention and cast the mind back to the time the invention was made (often as here many years), to occupy the mind of one skilled in the art who is presented only with the references, and who is normally guided by the then-accepted wisdom in the art." *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303, 313 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984).

IV. 35 U.S.C. 103(c) — EVIDENCE REQUIRED TO SHOW CONDITIONS OF 35 U.S.C. 103 APPLY

An applicant who wants to avail himself or herself of the benefits of 35 U.S.C. 103(c) has the burden of establishing that subject matter which qualifies as prior art under subsection (e), (f) or (g) of section

1993). See MPEP § 2112 for the requirements of rejections based on inherency.

PRIOR ART MUST BE CONSIDERED IN ITS ENTIRETY, INCLUDING DISCLOSURES THAT TEACH AWAY FROM THE CLAIMS

A prior art reference must be considered in its entirety, i.e., as a whole, including portions that would lead away from the claimed invention. *W.L. Gore & Associates, Inc. v. Garlock, Inc.*, 721 F.2d 1540, 220 USPQ 303 (Fed. Cir. 1983), *cert. denied*, 469 U.S. 851 (1984) (Claims were directed to a process of producing a porous article by expanding shaped, unsintered, highly crystalline poly(tetrafluoroethylene) (PTFE) by stretching said PTFE at a 10% per second rate to more than five times the original length. The prior art teachings with regard to unsintered PTFE indicated the material does not respond to conventional plastics processing, and the material should be stretched slowly. A reference teaching rapid stretching of conventional plastic polypropylene with reduced crystallinity combined with a reference teaching stretching unsintered PTFE would not suggest rapid stretching of highly crystalline PTFE, in light of the disclosures in the art that teach away from the invention, i.e., that the conventional polypropylene should have reduced crystallinity before stretching, and that PTFE should be stretched slowly.).

2141.03 Level of Ordinary Skill in the Art [R-2]

FACTORS TO CONSIDER IN DETERMINING LEVEL OF ORDINARY SKILL

"Factors that may be considered in determining level of ordinary skill in the art include (1) the educational level of the inventor; (2) type of problems encountered in the art; (3) prior art solutions to those problems; (4) rapidity with which innovations are made; (5) sophistication of the technology; and (6) educational level of active workers in the field." *Environmental Designs, Ltd. v. Union Oil Co.*, 713 F.2d 693, 696, 218 USPQ 865, 868 (Fed. Cir. 1983), *cert. denied*, 464 U.S. 1043 (1984).

The "hypothetical 'person having ordinary skill in the art' to which the claimed subject matter pertains would, of necessity have the capability of understanding the scientific and engineering principles applicable to the pertinent art." *Ex parte Hiyamizu*, 10 USPQ2d 1393, 1394 (Bd. Pat. App. & Inter. 1988) (The Board disagreed with the examiner's definition of one of ordinary skill in the art (a doctorate level engineer or scientist working at least 40 hours per week in semiconductor research or development), finding that the hypothetical person is not definable by way of credentials, and that the evidence in the application did not support the conclusion that such a person would require a doctorate or equivalent knowledge in science or engineering.).

References which do not qualify as prior art because they postdate the claimed invention may be relied upon to show the level of ordinary skill in the art at or around the time the invention was made. *Ex parte Erlich*, 22 USPQ 1463 (Bd. Pat. App. & Inter. 1992). >Moreover, documents not available as prior art because the documents were not widely disseminated may be used to demonstrate the level of ordinary skill in the art. For example, the document may be relevant to establishing "a motivation to combine which is implicit in the knowledge of one of ordinary skill in the art." *National Steel Car Ltd. v. Canadian Pacific Railway Ltd.*, 357 F.3d 1319, 1338, 69 USPQ2d 1641, 1656 (Fed. Cir. 2004)(holding that a drawing made by an engineer that was not prior art may nonetheless "be used to demonstrate a motivation to combine implicit in the knowledge of one of ordinary skill in the art").<

SPECIFYING A PARTICULAR LEVEL OF SKILL IS NOT NECESSARY WHERE THE PRIOR ART ITSELF REFLECTS AN APPROPRIATE LEVEL

If the only facts of record pertaining to the level of skill in the art are found within the prior art of record, the court has held that an invention may be held to have been obvious without a specific finding of a particular level of skill where the prior art itself reflects an appropriate level. *Chore-Time Equipment, Inc. v. Cumberland Corp.*, 713 F.2d 774, 218 USPQ 673 (Fed. Cir. 1983). See also *Okajima v. Bourdeau*, 261 F.3d 1350, 1355, 59 USPQ2d 1795, 1797 (Fed. Cir. 2001).